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17.1 INTRODUCTION

The Fundamental Purpose of the Generic Design Assessment (GDA) Safety, Security and Environment Case (SSEC) is to demonstrate that the generic Small Modular Reactor (SMR)-300 can be constructed, commissioned, operated, and decommissioned on a generic site in the United Kingdom (UK) to fulfil the future licensee's legal duties to be safe, secure and protect people and the environment, as defined in Part A Chapter 1, Introduction [1].

The Fundamental Purpose is achieved through the Fundamental Objective of the Preliminary Safety Report (PSR), which is to summarise the safety standards and criteria, safety management and organisation, claims, arguments and evidence to demonstrate that the generic SMR-300 design risks to people are likely to be tolerable and As Low as Reasonably Practicable (ALARP) [1].

PSR Part B Chapter 17 Human Factors, of the PSR presents the Claims, Arguments and Evidence (CAE) for the Human Factors (HF) topic.

17.1.1 Purpose and Scope

The Overarching SSEC Claims are presented in Part A Chapter 3, Claims, Arguments and Evidence [2].

This chapter (PSR Part B Chapter 17) links to the overarching claim through Claims 2.1 and 2.2:

Claim 2.1: The nuclear safety assessment identifies plant initiating events and specifies the requirements for safety measures such that safety functions are fulfilled, informs operational and emergency arrangements and demonstrates that risk is tolerable and ALARP.

Claim 2.2: The design of the systems and associated processes are developed taking cognisance of relevant good practice and substantiated to achieve their safety and non-safety functional requirements.

Human activities are implied in Claim 2.1. Claim 2.1.7 captures this aspect and is decomposed further to address identification and assessment of safety related actions.

Claim 2.1.7: Human actions important to safety and factors likely to influence human performance are systematically identified and their reliability and effective task performance is considered to be achievable.

As set out in Part A Chapter 3 [2], Claim 2.2 is further decomposed across several engineering disciplines responsible for development of the design of relevant Structures, Systems and Components (SSCs). This chapter presents the HF aspects for the generic SMR-300 and therefore directly supports claim 2.2.8, which focusses on the integration of HF related Relevant Good Practice (RGP) into the overall design and operation of SSCs.

Claim 2.2.8: Human factors requirements are integrated into the design, operation and maintenance of the Generic Holtec SMR-300.

Further discussion on how the Level 3 claims are broken down into Level 4 claims and how the Level 4 claims are met is provided in sub-chapter 17.3.

HF input has focused on the following workspaces, where the majority of SSCs are located:

- Reactor Auxiliary Building (RAB).
- Containment Structure (CS).
- Containment Enclosure Structure (CES).

Note: The SSCs for SMR-300 identified for PSR are captured in the Plant Breakdown Structure in PSR Part A Chapter 2 [3].

17.1.1.1 Reactor Auxiliary Building

The following areas of the RAB have been considered:

- Main Control Room (MCR), which is the area from which the key Human System Interfaces (HSIs) for the Plant Control System (PCS) and Plant Safety System (PSS) are controlled during all plant states.
- Remote Shutdown Facility (RSF), where the PCS and PSS are used to safely shutdown the plant in the event of the MCR being unavailable.
- Fuel Handling Area (FHA) from which fuel will be transported into the RAB, inspected and subsequently imported into the CS. This area is also used to initiate fuel drying and export used fuel.
- Areas associated with Reactor Systems which require human operation, e.g. the Primary Sampling System (PSL).

17.1.1.2 Containment Structure / Containment Enclosure Structure

The following areas and SSCs within the CS / CES were identified as being of high importance for GDA:

- Fuel Handling Systems.
- Areas associated with Reactor Systems which require human operation.
- Annular Reservoir (AR).
- Mechanical Handling Systems (Cranes).

These areas have been considered at a level judged to be appropriate for the maturity of the design for PSR. Further analysis by the United States (US) based Human Factors Engineering (HFE) team and the UK based HF team will be conducted as the design matures. HF related issues linked to installation, maintenance, testing and decommissioning of all SSCs will also receive input from both HF teams in a risk proportionate manner. The project position on Examination, Inspection Maintenance and Testing (EIMT) is presented in PSR Part B Chapter 9, Description of Operational Aspects and Conduct of Operations [4].

17.1.2 Chapter Overview

This chapter includes Identification of Human Failures (sub-chapter 17.4), Human Reliability Assessment (sub-chapter 17.5), Delivery of HF Input to SMR-300 Design (sub-chapter 17.6), Codes, Standards and Methodology (sub-chapter 17.7), Design Substantiation (sub-chapter 17.8), and Operating Philosophy and Concept of Operations (sub-chapter 17.9). Finally, a technical summary and summary of considerations against the ALARP principle is provided, together with any commitments that have arisen (sub-chapter 17.10).

A master list of definitions and abbreviations relevant to all PSR Chapters can be found in Part A Chapter 2, General Design Aspects and Site Characteristics [3].

17.1.3 Assumptions

There are no assumptions raised in relation to PSR Part B Chapter 17.

17.1.4 Interfaces with other SSEC Chapters

HFE has played an integral role in the development of SMR-300. As part of the development of this PSR the applicability of HFE activities and user-centred aspects of the design have been assessed against UK context across disciplines. This section provides a summary of how the HF topic interfaces with other PSR chapters.

Part A Chapter 2 General Design Aspects and Site Characteristics [3] describes the SMR-300 design including general information on the role of HF/HFE in the project. This chapter also includes information on the approach to metrication which has received input from the UK based HF team to provide guidance on ways to address the risk of human failures in conversion from metric to imperial units (and vice versa). Metrication is discussed further in sub-chapter 17.2.2.

Part A Chapter 4 Lifecycle Management of Safety and Quality Assurance (MSQA) [5] provides a description of all the processes and procedures undertaken for the SMR-300 Lifecycle MSQA, including the arrangements to manage quality, project and design. This highlights the integration of Human Factors input into the development of SMR-300 design and layout, as well as the SMR-300 organisational arrangements through Staffing and Qualification (S&Q) analysis.

Part A Chapter 5 Summary of ALARP [6] concludes that the SMR-300 demonstrably reduces risks to a level that is ALARP for this stage of the project. Furthermore, it confirms that the Fundamental Purpose of the System Safety and Environmental Case (SSEC) at PSR Version 1 has been achieved. The HF contribution is discussed further in sub-chapter 17.10.2.

PSR Part B Chapter 4 Control and Instrumentation Systems [7] provides evidence that the proposed Instrumentation and Control (I&C) HSIs will be designed in accordance with RGP. HF will also demonstrate that the proposed HSIs are informed by user needs and will not negatively influence human performance. The approach to incorporating HFE RGP into design is discussed further in Section 17.6.

PSR Part B Chapter 6 Electrical Engineering [8] requires HF input to demonstrate the suitability of workplaces to perform tasks and adequacy of the interface between system users and equipment. This input has centred around the application of HF RGP focusing on the need

to provide evidence of the application of EIMT guidance. The approach to incorporating HFE RGP into design is discussed further in Section 17.6.

PSR Part B Chapter 9 Description of Operational Aspects and Conduct of Operations [4] outlines operator roles and responsibilities, staffing levels, the design of EIMT, and general working arrangements such as administrative controls (including those linked to operating rules) and procedural documentation. These elements are guided by HFE processes, in line with U.S. Nuclear Regulatory Commission (NRC) expectations. Their applicability to the UK context has been evaluated and has influenced the development of Chapter 9. Section 17.9, which addresses the Operating Philosophy Review, is particularly relevant in this context.

PSR Part B Chapter 12 Nuclear Site Health and Safety (NSHS) and Conventional Fire Safety [9] demonstrates that conventional safety risks to personnel are reduced to a level that is ALARP. The overall approach to HF/HFE will be supplemented by evidence that the RGP, identified in the Nuclear Site Health and Safety topic area, has been applied to the elimination and mitigation of conventional health and safety risks. NSHS also requires HF input when considering arrangements for EIMT, to ensure adequate space and a suitable working environment are provided to workers. Further details are provided in Section 17.6.1, together with information on the development of a Target Audience Description (TAD) [10] and the Design Basis Review [11].

PSR Part B Chapter 14 Design Basis Accident Analysis [12] identifies the need for HF input to support the identification of Human Failures that could lead to design basis faults, as well as the identification and substantiation of any Human Actions (HAs) which are required to mitigate design basis faults. Further information on the approach for identification of human failures is discussed in Section 17.4 and the approach to Human Reliability Analysis (HRA) in Section 17.5.

PSR Part B Chapter 15 Beyond Design Basis, Severe Accident Analysis and Emergency Preparedness [13], also requires HF input for identifying potential Human Failures that could contribute to Beyond Design Basis Accidents (BDBAs), severe accidents or impact on emergency preparedness. HF is also required for identifying and justifying HAs necessary to mitigate against associated faults. This requirement is addressed under claim 2.1.7.2 and discussed in sub-chapters 17.4 and 17.5, which include the application of HRA.

PSR Part B Chapter 16 Probabilistic Safety Assessment [14] requires HF input to comment on the identification of Human Failures used within the Probabilistic Safety Assessment (PSA) as well as the quantification of human errors and the applicability of associated techniques for use in the UK. Further information on the approach to HRA is provided in Section 17.5.

PSR Part B Chapter 18 Structural Integrity [15] requires HF input to support decisions relating to the suitability of tasks linked to structural integrity (e.g. inspection for managing ageing and degradation), taking account of workspace equipment design, inspection tasks (including new or novel tasks) and competence requirements. Additionally, HF is required to support EIMT to demonstrate the through-life-reliability of the Higher Reliability SSCs. The approach to incorporating HFE RGP into design is discussed further in Section 17.6.

PSR Part B Chapter 19 Mechanical Engineering [16] requires HF input to demonstrate the suitability of the interface between system users and equipment taking account of workspace requirements. HF input has centred around the application of HF RGP focusing on the need

to provide evidence of the application of EIMT guidance. The approach to incorporating HFE RGP into design is discussed further in Section 17.6.

PSR Part B Chapter 20 Civil Engineering [17] requires HF input to support decisions relating to the suitability of workplaces (including the proposed layout of rooms and building footprint) and application of the associated RGP. The approach to incorporating HFE RGP into design is discussed further in Section 17.6.

PSR Part B Chapter 21 External Hazards [18] will require HF input to support the identification of any human failures that could lead to external hazards as well as the identification and substantiation of any HAs which are required to mitigate external hazards. This is also addressed as part of claim 2.1.7.2 and is discussed further in Section 17.4 and HRA in Section 17.5.

PSR Part B Chapter 22 Internal Hazards [19] will require HF input to support the identification of any human failures that could lead to internal hazards as well as the identification and substantiation of any HAs which are required to mitigate internal hazards. This will also be addressed as part of claim 2.1.7.2 and is discussed further in Section 17.4 and HRA in Section 17.5.

PSR Part B Chapter 23 Reactor Chemistry [20] may require HF to identify and assess the risk of human failures linked to associated faults. Where there are dependencies on HAs to perform safety significant functions associated with Reactor Chemistry, these will be systematically identified and assessed in support of future licensing phases.

PSR Part B Chapter 25 Construction and Commissioning [21] will support claims on the achievability of human activities and can be used to develop user trials. Detailed input is not expected to be provided until subsequent stages of design.

17.2 OVERVIEW OF HUMAN FACTORS

HF is the study of the environmental, organisational and job factors, along with human and individual characteristics that influence human performance. A significant proportion of accidents are attributed to, or influenced by, human error and organisational factors. The correct application of HF helps to match the capabilities of the human operator to the design and operation of the plant, optimising human performance and minimising the potential for Human Failure. For the SMR-300 the key subjects considered in this PSR include the safety significance of HAs, optimisation of system design for operation and maintenance tasking, staffing, qualifications and human reliability.

A key aspect of the process for licensing nuclear facilities in both the US and the UK is demonstrating RGP relating to the discipline of HF has been applied in a systematic manner. For the SMR-300 GDA it is therefore important that a clear basis for establishing the human contribution to safety, security and environment is provided across its lifecycle. This helps to ensure SSCs, and the overall Operating Philosophy takes cognisance of human performance limitations, thus cognisance of the risk of human failure.

The process for delivery of HF input is described in the Holtec HFE Program Management Plan (PMP) [22], which was written for the SMR-160 design and will be updated for SMR-300 in due course, noting that the same approach to HFE will be adopted for both reactor designs.

It is recognised that due to the cross-cutting nature of HF, early involvement is key to support decision making and the successful delivery of support to the project. PSR activities are therefore treated as an essential step towards HF objectives.

There are differences in the approach to licensing used by the US and UK Nuclear regulators, which mean that adherence to the NRC processes alone may not provide sufficient confidence of alignment against UK regulatory expectation. However, the goal-setting framework provided in the UK allows for the use of approaches such as that described in NUREG-0711, provided there is clear evidence as to why the approach used aligns with relevant guidance, as outlined in the ONR Safety Assessment Principles (SAPs) [23].

17.2.1 SMR-300 Approach to Passive Safety

Holtec SMR-300 GDA Passive Systems Report (HI-2241588) [24] describes the passive safety features incorporated in the SMR-300 design. These passive safety features are designed to eliminate the reliance on operator actions for a period of 72 hours post fault initiation. The demonstration that the design and operation of passive safety features reduces the risks to ALARP, assuming no operator actions, will be demonstrated as part of the Deterministic and Probabilistic Safety Assessments undertaken at Pre-Construction Safety Report (PCSR), with appropriate support from HF engineering teams.

The Top Level Plant Design Requirements (HI-2240251) [25] document outlines the three design philosophies for SMR-300 and then together with plant objectives and Electric Power Research Institute (EPRI) guidance provides design requirements which drive the layout / configuration of the plant as described in Part A Chapter 2 [3]. The safety philosophy and passive objective set for the plant in response to Design Basis Accidents (DBAs) is set out explicitly as plant requirement #1001:*"The plant design shall rely on passive means to mitigate design basis accidents".* This passive safety doctrine has had the largest influence on layout

of the SMR-300 (especially AR/ultimate heat sink/Passive Core Cooling (PCC) spatial arrangement and design).

17.2.2 Metrication

A systematic review of metrication issues has been undertaken across all disciplines, which has included identifying HF risks that are cross-cutting. The cross-cutting nature of HF necessitates an integrated approach to HFE, and alignment across engineering disciplines. The risks identified have been rationalised into key areas relating to HF topics such as Human Machine Interface (HMI) design, operating and maintenance procedures and operator training. The review concludes that these risks are manageable through application of RGP HF methodology, but that further work will be required beyond GDA Step 2 where established design constraints will facilitate more granular system-level evaluations.

Part A Chapter 2, General Design Aspects and Site Characteristics [3] provides a description of the metrication approach being adopted for SMR-300. The Metrication Hazard Assessment Process and Affected Areas report (HI-2241564) [26] describes the HF framework for identifying HF risks. The Metrication Pilot Study Analysis Report (HI-2241407) [27] identifies HF strategies and controls that represent HF RGP that will be used to facilitate future metrication Hazard Identification (HAZID) activities.

17.3 HUMAN FACTORS CLAIMS, ARGUMENTS AND EVIDENCE

Claim 2.1.7: Human actions important to safety and factors likely to influence human performance are systematically identified and their reliability and effective task performance is considered to be achievable.

Claim 2.1.7 has been further decomposed within PSR Part B Chapter 17, across the design lifecycle, to provide confidence that the relevant requirements will be met during all lifecycle phases. This has been done by breaking Claim 2.1.7 down into the following Level 4 claims:

Claim 2.1.7.1: Human failures shall be systematically identified using Relevant Good Practice methodologies in a risk proportionate manner.

Claim 2.1.7.2: Human Reliability Assessment shall be undertaken to determine the reliability and effective task performance of HAs in a risk proportionate manner.

Claim 2.2.8: Human factors requirements are integrated into the design, operation and maintenance of the generic Holtec SMR-300.

Claim 2.2.8 has been further decomposed within PSR Part B Chapter 17, across the design lifecycle, to provide confidence that the relevant requirements will be met during all lifecycle phases. This has been done by breaking Claim 2.2.8 down into four further Level 4 claims that help to define consistent criteria to be applied across all aspects of the design process:

Claim 2.2.8.1: Human Factors Relevant Good Practice is appropriately integrated into the generic Holtec SMR-300 lifecycle.

Claim 2.2.8.2: Human Factors design and assessment shall take cognisance of Relevant Good Practice and Operational Experience.

Claim 2.2.8.3: Requirements relevant to Human Factors are identified and substantiated in a risk proportionate manner.

Claim 2.2.8.4: Staffing and Qualification requirements are systematically assessed and informed by Human Reliability Assessment.

Table 1 shows the breakdown of Claims 2.1.7 and 2.2.8 and identifies in which chapter of this PSR these claims are demonstrated to be met to a maturity appropriate for PSR v1.

Table 1: Claims covered by PSR Part B Chapter 17

Claim No.	Claim	Sub-chapter
2.1.7.1	Human failures shall be systematically identified using Relevant Good Practice methodologies in a risk proportionate manner.	17.4 Identification of Human Failures
2.1.7.2	Human Reliability Assessment shall be undertaken to determine the reliability and effective task performance of human actions in a risk proportionate manner.	17.5 Human Reliability Assessment
2.2.8.1	Human factors Relevant Good Practice is appropriately integrated into the generic Holtec SMR-300 lifecycle.	17.6 Delivery of Human Factors Input to SMR-300 Design

Claim No.	Claim	Sub-chapter
2.2.8.2	Human Factors design and assessment shall take cognisance of Relevant Good Practice and Operational Experience.	17.7 Codes, Standards and Methodologies
2.2.8.3	Requirements relevant to Human Factors are identified and substantiated in a risk proportionate manner.	17.8 Design Substantiation
2.2.8.4	Staffing and Qualification requirements are systematically assessed and informed by Human Reliability Assessment.	17.9 Operating Philosophy and Concept of Operations

Appendix A provides a full Claims, Arguments and Evidence mapping for PSR Part B Chapter 17, which includes any lower-level claims, arguments and evidence needed to support the claims in the table above. This includes identification of evidence available at PSR v1 and aspects for future development of evidence to support these claims beyond PSR v1.

17.4 IDENTIFICATION OF HUMAN FAILURES

Claim 2.1.7.1: Human failures shall be systematically identified using Relevant Good Practice methodologies in a risk proportionate manner.

Claim 2.1.7.1 has been further decomposed into four arguments to address the claim:

- The Holtec approach to identifying HAs shall be reviewed to determine its suitability for a UK based design (A1).
- The output of the Holtec Treatment of Important Human Actions (TIHA) process, available for PSR, shall be reviewed to determine its suitability for a UK based facility (A2).
- The list of human failures captured in the SMR-160 PSA, Deterministic Safety Assessment (DSA) and Defence in Depth (DiD) analysis will be reviewed, along with the process used for their identification, and compared with the approach used in the UK (A3).
- A strategy will be developed and implemented to ensure human failures are identified in a systematic manner for the safety justification of a UK based design, making use of existing HRA data where possible (A4).

Argument 2.1.7.1 - A1: The Holtec approach to identifying Human Actions shall be reviewed to determine its suitability for a UK based design.

17.4.1 Evidence for Argument 2.1.7.1 – A1

Holtec SMR-300 GDA, Approach to Allocation of Function for SMR-300 (HI-2240728) [28]

The Approach to Allocation of Function, which is a key part of identifying those elements of the system that are reliant on human input, presents findings from a review that included assessing how Function Allocation (FA) and Functional Requirements Analysis (FRA) are used to identify a list of HAs. Review of these processes against RGP such as ONR Technical Assessment Guides (TAG) [29] demonstrates that a systematic process informed by Operational Experience Reviews (OER) is in place to identify HAs included within the scope of the Holtec HFE process.

Human Reliability Assessment Step 2 Position Statement (HI-2240725) [30]

The HRA Step 2 Position Statement [30] presents an overarching summary of the approach for assessing human-risk contribution to the design of the SMR-300, focusing on examples linked to the implementation of the process that were available for the development of the PSR.

Appendix A of the HRA Position Statement presents an example of the Holtec process for qualitative and quantitative analysis of SMR-300, used to identify the human activities associated with the Main Steam System (MSS). Functional decomposition and allocation for the MSS has been undertaken to identify the HAs required for operation of the system. This is presented in the HF Engineering FRA and FA for MSS report for SMR-160 (HI-2210351) [31]. Task Analysis (TA) of the MSS is also presented in the same report. This provides evidence that a systematic process for the identification of HAs is being applied.

17.4.2 Narrative

HAs important to safety and administrative controls are commonly referred within the UK nuclear industry as Human Based Safety Claims (HBSC). The NRC approach for HRA does not have an equivalent of HBSCs, but Safety Actions (SA) from the UK nuclear regulatory framework and can be viewed as equivalent to HAs. This is further discussed in section 17.10.2.1.

The identification of HAs is currently being undertaken by the following workstreams within SMR-300 design, all of which are supported by the HFE team using the approaches reviewed in the documents referred to in the previous section. These include:

- Plant Level Functional Identification / Decomposition.
- Functional Requirement Analysis.
- FA.
- Probabilistic analyses.
- Deterministic analyses.
- DiD Analyses.

The FA workstream may allocate functions to manual control, or place requirements on the design of automated functions (or automated elements of a function) to ensure system users maintain situational awareness. The FA process adopted by Holtec describes system functions in terms of 'Actions' that are required to satisfy the function, which can be used to identify HAs from manual actions. The reviews have confirmed that no Important Human Actions (IHAs) are claimed in the deterministic assessment.

The key steps in the Holtec approach to identifying HAs has been shown to be aligned with that typically used in the UK HRA process. The following work will be undertaken to meet UK RGP once further information becomes available:

- Produce a Fault Schedule that includes operator SAs (see PSR Part B Chapter 14 for more information).
- Review the DSA/PSA/DiD assessments to identify any HAs.

The evidence above supports the claim that the Holtec approach to identifying HAs has been reviewed to determine its applicability for a UK based design.

Argument 2.1.7.1 – A2: The Holtec process for Treatment of Important Human Actions (TIHA) shall be reviewed to determine its suitability for a UK based facility.

17.4.3 Evidence for Argument 2.1.7.1 – A2

Holtec SMR-300 GDA, HRA Methodology Review (HI-2240726) [32]

The HRA methodology review provides a review of Holtec approach to HRA and makes a comparison to UK regulatory expectation. It concludes that the identification of IHAs for SMR-300, as defined in the HFE PMP [22], incorporates aspects of Human Factors Integration (HFI) as well as some of the initial steps expected within UK HRA process.

The review notes that much like the UK approach to HFE, TA and TIHA support both DSA as well as PSA and set out a structured approach from the identification of human claims, risk ranking, followed by proportionate qualitative and quantitative assessment.

While the HRA methodology review does not draw conclusions on the adequacy of the approach, it provides evidence of a systematic and risk informed process, along with areas to focus future work.

Human Reliability Assessment Step 2 Position Statement (HI-2240725) [30]

The HRA Position Statement includes consideration of TIHAs, and examples of FA and TA output for the SMR-160 MSS to demonstrate the application of these techniques, providing evidence of how the approach is used in practice. It is noted that to date the Holtec HFE team have not identified any HAs in the DSA and PSA that are defined as an IHA. This is based on a review of all the safety related and DiD systems modelled in the DSA and PSA for the SMR-300 design.

17.4.4 Narrative

The TIHA process provides a determination on whether HAs are risk significant using both deterministic and probabilistic criteria. Deterministic IHAs are identified in the following deterministic analyses as specified in the SMR-160 HFE PMP [22]:

- HAs claimed in accident and transient analysis.
- Actions identified in the DiD Coping Analysis.

Actions relating to ‘Critical Safety Functions’ (i.e. reactivity control, core cooling, Reactor Coolant System (RCS) integrity, radioactivity control and containment condition) are selected as deterministically important.

Probabilistically assessed Human Failure Events from Level 1 (core damage) and Level 2 PSA for power generation, low power, and shutdown are assessed against risk importance criteria and sensitivity analyses.

To minimise the likelihood of significant human error and facilitate commensurate error detection and recovery capabilities, IHAs are explicitly addressed by the HFE program in FA, TA, HMI Design, HF Verification and Validation (V&V), Design Implementation and Human Performance Monitoring.

TIHA exists as an additional workstream to routine TA to ensure that detailed HRA is undertaken, with specific attention and prioritisation of effort given to FA, TA, HMI design and HF V&V.

No HAs identified in the generic SMR-300 DSA and PSA are defined as IHA and therefore no detailed assessment is available in support of GDA Step 2. However, the comparative review of UK and US-aligned HRA methodologies concludes that the identification of IHAs uses equivalent techniques and criteria to those typically adopted in the UK to determine risk significance.

The evidence above supports the claim that a review of the Holtec TIHA process has been undertaken to determine its applicability for a UK based facility.

Argument 2.1.7.1 – A3: The list of human failures captured in the SMR-160 Probabilistic Safety Assessment, Deterministic Safety Assessment and Defence in Depth analysis will be reviewed, along with the process used for their identification and compared with the approach used in the UK.

Argument 2.1.7.1 – A4: A strategy will be developed and implemented to ensure human failures are identified in a systematic manner for the safety justification of a UK based design, making use of Human Reliability Analysis (HRA) data where possible.

17.4.5 Evidence for Argument 2.1.7.1 – A3 and A4

SMR-160 PSA Human Reliability Analysis (HI-2210100) [33]

The SMR-160 PSA HRA report includes a summary of the process used for identification and evaluation of the SMR-160 Pre-Initiator and Post-Initiator Human Failure Events, which provides a reference point for determining the suitability of the approach for the UK. The SMR-160 draft system notebooks and system fault trees were analysed to identify Post-Initiator Operator actions compiled in Table 8-2 of the HRA analysis report [33]. This provides an example of information relating to human failures for the SMR-160 PSA, noting that the SMR-300 PSA information will not be available to support the PSR.

HRA Step 2 Position Statement (HI-2240725) [30]

The HRA Position Statement report [30] provides a high-level summary of the approach used to assess human risk contributions in the design of the SMR-300. As part of this review the four most risk significant systems were considered based on information available at the time of the review, captured in the DSA, PSA and DiD analysis. Appendix A also presents an example of the analysis of the MSS. A key part of this review was determining if the strategy for assessing human failures is systematic and aligned with guidance in ONR SAPs (primarily SAPs EHF 2 to 5 and EHF 10). While the review noted the limitations of the information available, no significant misalignments were noted at this stage.

Summary of Claims Placed on System Users for SMR-300 (HI-2240727) [34]

The Operational Task Schedule, described in this report will be used to capture HAs identified by assessments performed in the UK to align with UK expectations. To-date these assessments have not reached a sufficient level of maturity to perform detailed error analysis, however, the Holtec HF Team based in the UK have worked closely with the Fault Studies and PSA teams to establish the maturity of the UK based Fault Schedule and presentation of data relating to human failure used by the UK based PSA team. This has included ensuring dependencies between Fault Studies, PSA and HF are mapped in project plans.

17.4.6 Narrative

17.4.6.1 Identification of Human Failures in SMR-300 PSA, DSA and DiD Analysis

Holtec have reviewed the human failures within the SMR-160 PSA Human Reliability Analysis report (HI-2210100) [33] in support of an assessment of PSA best practice and confirmed they are appropriate. The HRA Position Statement [30], Statement 1, confirms that human failures

identified in the PSA model have received proportionate review. It also demonstrates that the significance will be informed by their contribution to nuclear safety, through alignment with DSA, PSA and DiD (discussed further in Statement 2). The HRA Position Statement provides a discussion under Statement 3 that “All identified HAs have received proportionate HF assessment commensurate with design maturity for GDA Step 2”. No issues were noted during this review regarding misalignment with ONR SAPs, noting limitations based on material available at the time of the assessment. This level of analysis is considered appropriate for the PSR and is discussed further in Statement 8 of the document.

Commitment C_Huma_003 has been raised within this chapter in response to the above evidence and to ensure that HRA is undertaken in line with UK expectations, to determine the reliability and effective task performance of HAs in a risk proportionate manner.

C_Huma_003: The SMR-300 design, and underlying design processes demonstrate that human risks are systematically identified, proportionately assessed, and that the risk contribution from operator actions is tolerable. It is noted that US HRA outputs for the SMR-300 will not be available for review within GDA timeframes and as such cannot be integrated with UK safety assessment processes which HRA must effectively support and integrate with. A Commitment is raised to develop a HRA Strategy for the UK SMR-300 design, describing how to make use of the processes for deterministic and probabilistic safety assessment used by the NRC, as well as information relating to the Treatment of Important Human Actions in UK safety assessment. Target for Resolution - Issue of UK Pre-Construction Safety Report.

17.4.6.2 Strategy for Identification of Human Failures for UK Context

The Summary of Claims Report presents the strategy for how human failures will be identified in a UK context. The Operational Task Schedule will be used to capture HAs identified by assessments performed in the UK. To-date these have not reached a sufficient level of maturity to perform detailed error analysis, however, the Holtec HF Team based in the UK have worked closely with the Fault Studies and PSA teams to establish the maturity of the UK based Fault Schedule and presentation of data relating to human failure used by the UK based PSA team. This has included ensuring dependencies between Fault Studies, PSA and HF are mapped in project plans.

Commitment C_Faul_103 has also been raised within PSR Part B Chapter 14 [12] to ensure a holistic and comprehensive approach to fault studies is undertaken, reflecting UK RGP and including appropriate HF assessments.

C_Faul_103: Holtec commit to ensuring that the repurposing of the US safety analyses undertaken for the Palisades SMR-300 design also considers and undertakes, as necessary, supplemental safety assessment to appropriately address UK expectations and good practice. This supplemental assessment should incorporate the full scope UK SMR-300 design and will be targeted to ensure a holistic and comprehensive approach across the recognised safety assessment disciplines. This will incorporate HFE analysis (including HRA) throughout Design Basis Accident Analysis (DBAA) / PSA / Severe Accident Analysis (SAA), which is a key part of ONR SAP EHF 10.

The evidence above supports the claim that human failures captured in the SMR-300 PSA, DSA and DiD analysis will be reviewed in a systematic manner, along with the process used for their identification and compared with the approach used in the UK. The commitments

highlighted above show that deficiencies in the maturity of HRA strategy and system failure analyses for a UK context are recognised and will be resolved by Holtec in support of GDA closure.

17.4.7 CAE Summary

The Holtec approach to identifying HAs is aligned with that typically used in the UK HRA process for the current stage in the project's lifecycle. However, the following further work will be undertaken to meet UK RGP:

- Develop a HRA strategy to support UK based safety assessment activities and use it to review the DSA/PSA/DiD assessments to identify HAs (C_Huma_003).
- Produce a Fault Schedule that includes operator SAs (C_Faul_103).

The Holtec design philosophy for SMR-300 includes the intent to minimise the reliance placed on the human to deliver nuclear safety. Structured qualitative and quantitative assessments are underway for SMR-300 design, as outlined in the HFE PMP [22], providing confidence that a systematic process is being applied to identify all risk significant HAs. The review of US-based HRA methodologies also concludes that the identification of IHAs uses equivalent techniques and criteria typically adopted in the UK to determine risk significance. However, these analyses will not be completed within the timescales of GDA and so commitments have been raised for further development of HRA strategy and integration of analysis into the UK safety assessment process.

Human failures captured in the SMR-300 PSA, DSA and DiD analysis will be identified in a systematic manner, compatible with UK RGP.

17.5 HUMAN RELIABILITY ASSESSMENT

Claim 2.1.7.2: Human Reliability Assessment shall be undertaken to determine the reliability and effective task performance of human actions in a risk proportionate manner.

Claim 2.1.7.2 has been further decomposed into three arguments to address the claim:

- The Holtec approach used to assess the risk of human failures will be reviewed and compared to UK regulatory expectations (A1).
- Output from Holtec HFE and HRA activities to be reviewed, and where appropriate used to demonstrate the risk linked to human failures is acceptable in line with good practice used in the UK (A2).
- A strategy will be developed and implemented to substantiate human failures in a systematic manner for safety justification of a UK based design, making use of Holtec HRA data where possible (A3).

Argument 2.1.7.2 – A1: The Holtec approach used to assess the risk of human failures will be reviewed and compared to UK regulatory expectations.

17.5.1 Evidence for Argument 2.1.7.2 – A1

Holtec SMR-300 GDA, HRA Methodology Review (HI-2240726) [32]

The HRA Methodology Review provides a discussion on the qualitative and quantitative HRA approach used for the SMR-300, comparing with ONR and Health and Safety Executive (HSE) guidance. The review highlighted 11 areas for further consideration and noted that whilst the processes applied are not completely equivalent to those used in the UK, they are systematic and in alignment with the NRC described process in NUREG-0711. This provides confidence that personnel actions are clearly and systematically identified and subsequently aligned with PSA and DSA (see figure 4-1 in the HFE PMP). The findings of the review formed the basis for further assessment in the Human Reliability Assessment Step 2 Position statement [30] and development of the Summary of Claims Placed on System Users for SMR-300 [34].

Human Reliability Assessment Step 2 Position Statement (HI-2240725) [30]

The HRA Position Statement report [30] provides a high-level summary of the approach used to assess human risk contributions in the design of the SMR-300. Statement 1 in the position statement confirms that identification of human safety related actions is undertaken using a systematic and robust process. Review of the approach used to assess human failures identified in the PSA model was conducted in support of this statement and concludes that human failures identified to date have received proportionate review, which is in line with ONR SAPs. Statement 2 addresses the classification process, highlighting differences in approach between the US and UK and the strategy by which these will be assessed. Statement 8 examines the HRA programme, demonstrating that there are no challenges likely to prevent the relevant SAPs from being achieved.

Summary of Claims Placed on System Users for SMR-300 (HI-2240727) [34]

The Summary of Claims presents a process for the development of an Operational Task Schedule which will serve as a live document to support the tracking and management of identified HAs in support of Nuclear Safety, Security, Environmental and Safeguards Claims in the UK for the SMR-300. It provides a clear trail showing how HAs are identified, characterised (in terms of risk significance), screened, assessed and represented in the DSA and PSA. It also provides a range of supplementary information that describes the key characteristics of each HA (including type, location, purpose and Human Error Probabilities (HEPs) if applicable) and a link between the actions and HFE assessments that generate HF related requirements.

17.5.2 Narrative

[REDACTED]

Further context on the significance of these claims in relation to the overall PSA Core Damage Frequency (CDF) is presented as part of Statement 7 in the HRA Position Statement [30].

The evidence above supports the claim that the Holtec approach used to assess the risk of human failures has been reviewed and compared to the approach used in the UK.

Argument 2.1.7.2 – A2: Output from Holtec HFE and HRA activities to be reviewed and where appropriate used to demonstrate the risk linked to human failures is acceptable in line with good practice used in the UK.

17.5.3 Evidence for Argument 2.1.7.2 – A2

Human Reliability Assessment Step 2 Position Statement (HI-2240725) [30]

Statement 7 of the HRA Position Statement [30] provides an overview of the human risk contribution for the SMR-300, based on the PSA analyses presented in the Holtec SMR-160 PSA Integration and Quantification Report (HI-2210104) [35]. The SMR-160 PSA Dependency Analysis and Recovery Rules (HI-2210111) [36] supports this document and provides the full set of importance data for each claimed HA.

17.5.4 Narrative

SMR-160 PSA sensitivity studies and importance metrics from Minimal Cut Sets (MCS) outlined in the HRA Position Statement [30] have been used to demonstrate the extent to which the SMR-300 design is reliant on the human, as well as the design tolerance to human error, noting that there are no HRA outputs available to review for SMR-300 at PSR V1.

These are documented in the Holtec SMR-160 PSA Integration and Quantification Report (HI-2210104) [35] and the SMR-160 PSA Dependency Analysis and Recovery Rules (HI-2210111) [36]. No IHAs have been identified to date, based on the probabilistic risk ranking criteria informed by these studies.

The analyses reviewed demonstrates, using quantitative and qualitative criteria, that the overall contribution to risk from HAs identified so far within SMR-300 design are not significant, and that the design does not place reliance on HA as the primary means to achieve nuclear safety. This conclusion was drawn solely for plant-based Design Basis faults. As further information is gathered in support of internal / external hazards and fuel route fault analysis any new claims on operator action will be reviewed to identify potentially important actions.

The evidence above supports the claim that Holtec HFE and HRA activities demonstrate the risk linked to human failures is acceptable and have been assessed in a systematic manner.

Argument 2.1.7.2 – A3: A strategy will be developed and implemented to substantiate human failures in a systematic manner for safety justification of a UK based design, making use of Holtec HRA data where possible.

17.5.5 Evidence for Argument 2.1.7.2 – A3

Holtec SMR-300 GDA, HRA Methodology Review (HI-2240726) [32]

The HRA Methodology Review presents examples of the HRA information produced by Holtec that could be used to substantiate human failures for the safety justification of a UK based nuclear facility. This includes discussion of qualitative analysis outputs including TA, FRA, OERs and TIHA outputs which should, where appropriate, be used to support the design of the plant, operational systems and administrative controls, as well as substantiation of the identified SAs. It should be noted that there are no HRA outputs available to review for SMR-300 at PSR v1.

Human Reliability Assessment Step 2 Position Statement (HI-2240725) [30]

The HRA Position Statement provides examples of a task description form, TA output and SPAR-H screening outputs that can be used as evidence of the feasibility of using existing HRA data.

Holtec SMR-300 GDA, Approach to Allocation of Function for SMR-300 (HI-2240728) [28]

The Approach to Allocation of Function presents a review between UK RGP and the FA methodologies applied by Holtec for the SMR-300 in support of the NRC Licensing Process.

17.5.6 Narrative

HRA outputs are available for the SMR-160 design only at GDA. Cross comparison of example SMR-160 outputs with UK expectations has been performed, with conclusions summarised in the sections immediately below and additionally in sub-section 17.6.3. These provide confidence that substantiation could be made in the future once SMR-300 specific HRA data becomes available. A GDA Commitment (C_Huma_003) has also been raised which will result in development of a strategy to effectively integrate the NRC context derived HRA outputs into the UK safety assessment and design of SMR-300.

C_Huma_003: The SMR-300 design, and underlying design processes demonstrate that human risks are systematically identified, proportionately assessed, and that the risk contribution from operator actions is tolerable. It is noted that US HRA outputs for the SMR-300 will not be available for review within GDA timeframes and as such cannot be integrated with UK safety assessment processes which HRA must effectively support and integrate with. A Commitment is raised to develop a HRA Strategy for the UK SMR-300 design, describing how to make use of the processes for deterministic and probabilistic safety assessment used by the NRC, as well as information relating to the Treatment of Important Human Actions in UK safety assessment. Target for Resolution - Issue of UK Pre-Construction Safety Report.

17.5.6.1 Functional Requirement Analysis Examples

FA is a key part of the substantiation process as the FA decision making process is focussed on how the function is controlled between human and automation. A UK review of FA processes and the interface between FA and TA is presented in the Approach to Allocation of Function Report [28], which presents a sampled review of FA assessments for the Spent Fuel Pool Cooling System (SFC), Passive Containment Heat Removal System (PCH), and the Containment Isolation System (CIS).

17.5.6.2 Task Analysis Examples

Section 4.5.4 of the HRA Methodology Review [32] discusses the methodology for undertaking TA and provides examples of the TA process adopted in the US. It provides examples of the Operational Sequence Diagram (OSD), and Task Requirement Forms used in the Holtec HRA approach. TA supports design substantiation as part of the HF Design Basis workstream where the HSI is shown to meet the Task Design requirements specified in the TA.

17.5.6.3 Operating Experience Review Examples

Learning from Experience (LfE) (obtained through OERs) is also used as a valid source of evidence to inform HA requirements, although the identification and use of LfE is not explicitly documented and captured as evidence.

17.5.6.4 Treatment of Important Human Actions Examples

The TIHA process provides a determination on whether HAs are risk significant using both deterministic and probabilistic criteria. Deterministic IHAs are identified in the following deterministic analyses as specified in the SMR-160 HFE PMP [22]:

- HAs claimed in accident and transient analysis.
- Actions identified in the DiD Coping Analysis.

Actions relating to 'Critical Safety Functions' (i.e. reactivity control, core cooling, RCS integrity, radioactivity control and containment condition) are selected as deterministically important.

Probabilistically assessed Human Failure Events from Level 1 (core damage) and Level 2 PSA for power generation, low power, and shutdown are assessed against risk importance criteria and sensitivity analyses.

Future work includes a commitment to produce a strategy to substantiate human failures in support of Holtec safety assessment activities for the UK. Commitment C_Huma_003 is raised to develop a HRA Strategy for the UK SMR-300 design describing how to make use of the processes for deterministic and PSA used by the NRC, as well as information relating to the TIHAs in UK safety assessment.

The evidence above supports the future development and implementation of a strategy to substantiate human failures in a systematic manner for safety justification of a UK based design, when relevant SMR-300 outputs become available.

17.5.7 CAE Summary

The majority of human failure events modelled in the SMR-160 PSA based on identified HAs have received treatment using either the ASEP or SPAR-H. The suitability of ASEP and SPAR-H to provide initial screening values for human failure events is discussed in the Step 2 HRA Methodology Review and these are considered to be fundamentally adequate methods.

PSA analyses demonstrate that the overall contribution to risk from HAs is not significant, and the design does not place reliance on HA as the primary means to achieve nuclear safety.

The substantiation of risk significant human failures has not been feasible at GDA due to a lack of reliance on HAs within the fundamental SMR-300 design. In addition, HRA output for SMR-300 will need to be integrated with UK safety assessment processes to generate confidence in the proposed process against UK regulatory guidance for HRA, such as SAP EHF 10. This is reflected in the GDA commitment raised against Argument A3 (C_Huma_003).

17.6 DELIVERY OF HUMAN FACTORS INPUT TO SMR-300 DESIGN

Claim 2.2.8.1: Human Factors Relevant Good Practice is appropriately integrated into the generic Holtec SMR-300 lifecycle.

Claim 2.2.8.1 has been further decomposed into four arguments to address the claim:

- The Holtec SMR-300 HFE PMP [22] provides a framework for systematic delivery of HF RGP which has been reviewed to determine its applicability for a UK context (A1).
- Holtec HF Team based in the UK have reviewed the SMR-300 FA and TA to ensure HAs are assessed and allocated in a systematic and risk proportionate manner. This approach has been considered against RGP, highlighting any additional activities required for UK context (A2).
- A Holtec Britain Human Factors Integration Plan has been developed to support GDA so that HF integration can be achieved for the SMR-300 within a UK context (A3).
- HFE related issues are tracked using the HFE Issue Tracking System (HITS) database, which is overseen by the US based HFE team and accessible to the UK based HF team. HF issues and assumptions identified during UK specific activities are being tracked and fed into US design decisions in a risk proportionate manner (A4).

Argument 2.2.8.1 – A1: The Holtec SMR-300 HFE PMP [22] provides a framework for systematic delivery of HF RGP which has been reviewed to determine its applicability for a UK context.

17.6.1 Evidence for Argument 2.2.8.1 – A1

SMR-160 Human Factors Engineering Program Management Plan (HPP-160-1014) [22]

The HFE activities undertaken by Holtec for the generic SMR-300 have been carried out in accordance with the NUREG-0711 and are documented in the HF Engineering Program Review Model [37]. NUREG-0711 is considered best practice by the NRC and provides a robust basis for delivery of HF RGP to the SMR-300. NUREG-0711 is also recognised by the ONR as a prescribed approach for HF Integration.

The HFE PMP [22] provides a process for identifying and assessing HAs key to maintaining the safe operating envelope for SMR-300. In conjunction with the Operational Task schedule proposed in the Summary of Claims submission [34], the output from this process can be used to identify administrative controls with a clear link to associated nuclear related hazards (i.e. SAP EHF.4). These will inform the content of procedures required for development within the HFE PMP in support of reliable human performance (i.e. SAP EHF 9).

The HFE PMP [22] also refers to the process for development of procedures after HFE V&V. Whilst the licensee will have ultimate responsibility for their development, the HFE PMP outlines the activities to be performed and the associated outputs that will inform procedural content.

It is noted the HFE PMP [22] presented for GDA is for SMR-160 rather than for SMR-300. This is primarily due to a misalignment of timescales for HFE PMP update and completion of GDA. The activities listed in this document are primarily related to the HFE process rather than

details relating to the design of the plant. The HFE PMP scope will remain largely unchanged for SMR-300 and the SMR-160 version is considered to provide suitable evidence of the approach for a PSR level review. The PMP for SMR-300 is expected to be available for the PCSR.

Holtec SMR-300 Generic Design Assessment, Human Factors Integration Plan for Generic Design Assessment (HI-2240723) [38]

The Early Human Factors Assessment (EHFA), documented in Appendix A of the GDA Step 2 HFIP, provides a high-level review of the SMR-300 design and activities outlined in the HFE PMP. This review confirmed that the HFE PMP [22] provides evidence that a systematic process is being implemented by a dedicated HFE team. It also demonstrates that the HFE PMP is broadly aligned with the key Human Factors topics outlined in ONR SAPs.

The EHFA also highlighted the need for HF input into metrication, ongoing UK engagement with the US-based HFE team, and improved visibility of HFE documentation, including the HITS database. These findings informed further activities carried out in support of the PSR listed in the HFIP, all of which have since been addressed and are discussed further in Section 17.6.7.

Holtec SMR-300 Generic Design Assessment, Human Reliability Assessment Methodology Review (HI-2240726) [32]

The HRA Methodology Review presents a comparative review of the frameworks used for identifying and assessing the risk of human failures within the Holtec HFE programme against UK context. This includes a review of TA, TIHA and HRA methodologies against ONR guidance.

The document demonstrates that a systematic process is in place for performing HRA. It also highlights areas where the approach used by Holtec, which is based on NRC guidance, does not completely align with UK guidance. However, this mis-alignment is considered to be manageable in subsequent phases of SMR-300, supported by delivery of GDA commitment C_Huma_003 design (see Sections 17.4 and 17.5 for further discussion).

Holtec SMR-300 GDA, Operating Philosophy Review (HI-2240731) [39]

The Operating Philosophy Review summarises the available information on operator roles and responsibilities, staffing levels and the use of key facilities for SMR-300 operation which is referred to as the ‘Operating Philosophy’. This provides information regarding the basis of assumed staffing levels as well as roles and responsibilities. These are primarily based on those used in existing NRC regulated Pressurised Water Reactors, and methodologies for deviations from these requirements. The HFE process is key to these activities and provides broad alignment with guidance in ONR SAPs on staffing (e.g. EHF 5 and EHF 11).

The Operating Philosophy Review is an interim report and provides similar information to that which will be provided in the SMR-300 Concept of Operations (Con Ops). This will include how the operating crew is organised and how it monitors and controls the plant during normal operations, Anticipated Operational Occurrences (AOO), and faulted conditions. The SMR-300 Con Ops is expected to support this claim in future iterations of the SSEC.

Holtec SMR-300 GDA Target Audience Description (HI-2240729) [10]

The TAD provides a preliminary description of the expected UK user population and relevant guidance to provide a baseline against which comparisons between UK guidance and Holtec documents can be undertaken. The document provides a point of reference to make comparisons between UK and US guidance, where guidance based on a US population has been used to inform the SMR-300 design, to demonstrate the applicability of SMR-300 design for use in the UK.

Holtec SMR-300 GDA Human Factors Design Basis Review (HI-2240732) [11]

The Design Basis Review makes a comparison between HFE related guidance used to inform the design and the equivalent UK standards. This review is based on information obtained for the TAD and information presented in Holtec HFE documentation. The output of the review highlights a broad alignment in a number of areas and some differences in HFE related criteria that could impact on workspace and task design. The review demonstrates applicability of the framework used for delivery of HFE for a UK context.

17.6.2 Narrative

The approach undertaken for SMR-160 provides confidence that a framework for delivery of HF RGP to SMR-300 is in place and is being implemented. The preliminary reviews carried out to support PSR also provide confidence that this is broadly aligned with UK licensing expectations, including those linked to development of operating rules and procedures, which are key to ONR guidance on Administrative controls (EHF 4) and Procedures (EHF 8). While there are still some gaps in the information available at GDA the information reviewed so far provides confidence that a systematic approach is being taken.

The reviews presented in the Step 2 deliverables demonstrate that approaches adopted by Holtec those expected within UK regulatory context are similar. Where differences exist HF considerations have been captured in the relevant documents and escalated to the project risk or Commitments, Assumptions and Requirements (CAR) register. Any required design changes are then managed in accordance with the Holtec Design Management Process [40].

The HFIP, including the EHFA, helped to provide a basis for GDA Step 2 HF topic activities. The HRA Methodology Report provides insight into the systematic approach to HRA used for SMR-300. The Operating Philosophy Review has provided insight into the systematic approach to development of a concept of operations and staffing levels for SMR-300. These are considered to provide sufficient evidence to support PSR.

The development of the TAD and design basis review highlights UK specific guidance applicable to any workplace and providing clarity on where potential gaps may exist for workspaces in SMR-300. It demonstrates where guidance is broadly applicable and where there may be areas for further consideration during detailed design.

The evidence above supports the claim that Holtec's systematic HFE approach has been reviewed against UK RGP and shown to be broadly equivalent.

Argument 2.2.8.1 – A2: Holtec HF Team based in the UK have reviewed the SMR-300 Function Allocation (FA) and Task Analysis (TA) to ensure human actions are assessed and allocated in a systematic and risk proportionate manner. This approach has been considered against RGP, highlighting any additional activities required for UK context.

17.6.3 Evidence for Argument 2.2.8.1 – A2

Holtec SMR-300 GDA, Approach to Allocation of Function for SMR-300 (HI-2240728) [28]

The Approach to Allocation of Function presents a review of the FA methodologies applied by Holtec for the SMR-300 in support of the NRC Licensing Process against ONR guidance. This demonstrates that there is a broad equivalence between Holtec processes and UK RGP, providing confidence that the methodologies are able to produce evidence that would be generally suitable for the SMR-300 within a UK regulatory context.

The HF considerations identified in the report do not challenge the fundamental adequacy of SMR-300 design at GDA, and the level of detail in FA assessments is considered broadly proportionate for the current design maturity.

Human Reliability Assessment Step 2 Position Statement (HI-2240725) [30]

Holtec provided documentation linked to FA and TA activities for four key systems as examples of the HRA process, the review of which is presented in the HRA Position Statement [30]. The systems analysis included MSS, PCC, Residual Heat Removal System (RHR) and the SFC. The review of these documents provided insight into how HAs associated with the most significant SSCs have been assessed. The scope of assessment demonstrated the systematic application of a broadly robust process as determined by the HRA Methodology Review. FA and TA for SMR-300 will be reviewed after GDA Step 2 as further information becomes available.

Appendix A of the HRA Position Statement also presents an example of the qualitative and quantitative analysis process for SMR-300, including example outputs of TA and HRA methodologies. This level of detail provides confidence of HAs being allocated and assessed in a systematic and risk proportionate manner, which is aligned with ONR guidance for allocation of SAs (e.g. SAP EHF 2) and analysis of human reliability (e.g. SAP EHF 10).

17.6.4 Narrative

The Approach to Allocation of Function for SMR-300 assesses the approach to FA and TA used by the HFE team. This demonstrates that there is a broad equivalence between Holtec processes and UK RGP, providing confidence that the methodologies can produce evidence that would be generally suitable for licensing in the UK.

The review of output from HFE analysis of four key systems in development of the HRA Position Statement, with examples provided in Appendix A, provide confidence in the implementation of systematic approaches to FA and TA as outlined in the HFE PMP and the HRA Methodology Review. FA and TA outputs for SMR-300 will be reviewed after GDA Step

2 as further information becomes available, however, the current level of evidence is considered sufficient for PSR.

The evidence above supports the claim that the Holtec HF Team based in the UK have carried out a review of FA and TA and concluded that it is conducted in a risk proportionate manner.

Argument 2.2.8.1 – A3: A Holtec Britain Human Factors Integration Plan has been developed to support GDA so that HF integration can be achieved for the SMR-300 within a UK context.

17.6.5 Evidence for Argument 2.2.8.1 – A3

Holtec SMR-300 GDA, Human Factors Integration Plan for GDA (HI-2240723) [38]

A HFIP was produced to capture activities for the GDA process to highlight the preliminary strategy for GDA step 2 activities. The activities listed, which developed on those first identified in the HF Technical Engagement Plan for GDA Step 2 [41], helped to target HF support, track HF related issues in a systematic manner and provide evidence of the approach used. The HFIP provides evidence to support the claim that HF RGP is integrated into the SMR-300 in a manner that is appropriate for the UK.

17.6.6 Narrative

The HFIP was produced in the preliminary stages of GDA Step 2 to define the scope of work to be undertaken during Step 2. This was based on the conclusion of GDA Step 1 activities. The activities in the HFIP have now been completed and associated HF considerations are identified in Step 2 deliverables. These have been sentenced and taken forward into the CAR Register [42] (further discussed in 17.6.7) where appropriate.

HF integration into SMR-300 lifecycle management and quality assurance process is also demonstrated in section 17.8.2 on HF requirements derivation and in PSR Part A Chapter 4 [5] on Human Factors input into the development of building layout and organisational arrangements.

The evidence above supports the claim that the HFIP has been developed so that HF integration can be achieved for the SMR-300 within a UK context for GDA.

Argument 2.2.8.1 – A4: HFE related issues are tracked using the HITS database, which is overseen by the US based HFE team and accessible to the UK based HF team. HF risks, issues and assumptions identified during UK specific activities are being tracked and fed into US design decisions in a risk proportionate manner.

17.6.7 Evidence for Argument 2.2.8.1 – A4

Risk Management Plan (HI-2241492) [43]

HF considerations raised as a result of Step 2 assessment have been reviewed and the Holtec risk management process [43] applied to identify all potential risks associated with these considerations for design. This document discusses the process for risk management during the SMR-300 GDA. HF risks are identified on the Holtec GDA Risk Register and will be managed in accordance with the risk management process as the project moves beyond GDA Step 2.

Holtec SMR-300 GDA Capturing and Managing Commitments, Assumptions and Requirements (HPP-3295-0013) [42]

Any HF considerations that highlight changes required to fundamental aspects of the SMR-300 design, design process, or operational characteristics, specifically those necessary to meet UK context requirements within the scope of GDA, have been identified as commitments. Commitments, Assumptions and Requirements are identified in the CAR Register [42].

17.6.8 Narrative

HF considerations identified in Step 2 reports and during early iterations of the Risk Register have been logged, assessed and documented. The Holtec risk management process [43] has been applied to identify all potential risks associated with HF considerations, which have been captured in the Risk Register. Where relevant, considerations that involve changes to fundamental aspects of the SMR-300 design, design process, or operational characteristics, specifically those necessary to meet UK context requirements within the scope of GDA, have been identified as commitments. One commitment has been raised under the HF topic and is documented in the CAR Register [42] (C_Huma_003).

The evidence above supports the claim that HF risks will be tracked to ensure any issues, including identified gaps in RGP are mitigated.

17.6.9 CAE Summary

The main aspect of the HF work undertaken by the Holtec HF team based in the UK has been reviewing the HFE process, as defined in the SMR-160 HFE PMP [22] against UK regulatory expectations for HF integration and analysis. The reviews presented in the Step 2 deliverables demonstrate that the approach to HF will largely meet UK regulatory expectations, but there are differences at a more detailed level. HF considerations have been raised and logged in either the project Risk Register [43].

The Approach to Allocation of Function review includes a review of systematic FA and TA process for four of the most risk significant systems.

An HFIP was produced early in GDA Step 2 to define the scope of work to be undertaken. This work has now been completed and a number of HF considerations identified. These have been sentenced and taken forward into the CAR Register [42], where required.

HF considerations identified in the Step 2 deliverables will be tracked into future design and licensing phases by use of the project Risk Register [43], ensuring that minor deviations from UK RGP will be managed and addressed appropriately beyond GDA Step 2.

17.7 CODES, STANDARDS AND METHODOLOGIES

Claim 2.2.8.2: Human Factors design and assessment shall take cognisance of Relevant Good Practice and Operational Experience.

Claim 2.2.8.2 has been further decomposed into one argument to address the claim that the HF delivery framework for SMR-300 has been compared against the ONR SAPs.

Argument 2.2.8.2 – A1: SMR-300 has been based on the HF delivery framework identified by NUREG-0711. This will be compared against the Safety Assessment Principles provided by ONR to confirm its applicability for the UK Context.

17.7.1 Evidence for Argument 2.2.8.2 – A1

SMR-160 Human Factors Engineering Program Management Plan (HPP-160-1014) [22]

This document defines the HFE delivery framework used by the HFE team to inform the design of the SMR-300. The HF PMP is based on meeting NUREG-0711 [37] and other international HF related guidance including the Human-System Interface Design Review Guidelines (NUREG-0700) [44] and OERs.

Appendix A.2 of the PMP describes a process for identifying HFE-related safety issues by analysing the lessons learned (Learning from Experience (LfE) from existing facilities as part of OER reviews. This includes LfE from predecessor plants and/or systems from both Pressurised Water Reactors (PWRs) as well as related power generation facilities. The output from these reviews is captured in Results Summary Reports shared with the other disciplines involved in the design process. Additional sources of information include incident logs taken from NRC regulated sites, as well as publications from EPRI and the Institute of Nuclear Power.

Holtec SMR-300 GDA, Human Factors Integration Plan for GDA (HI-2240723) [38]

The EHFA carried out as part of the HFIP includes a review of the HFE PMP [22] activities against the ONR SAPs. The conclusion of this was that the activities in the PMP are broadly aligned with UK expectations. The most significant differences related to the approach to HRA, which is discussed further in Sections 17.4 and 17.5. It is also noted that there will always be minor differences between the populations and associated conventions used in HFE related guidance specific to a particular country, which prompted the production of an SMR-300 TAD [10] for the UK work force and a review of associated UK specific guidance against US guidance in the Design Basis Review [11].

Holtec SMR-300 GDA Target Audience Description (HI-2240729) [10]

The TAD provides a preliminary description of the expected UK workforce as well as relevant Standards and Guidance directly applicable to the UK that are relevant to HF. This provides a baseline against which comparisons between UK HF RGP and Holtec HFE guidance could be made within the Design Basis Review [11].

Holtec SMR-300 GDA Human Factors Design Basis Review (HI-2240732) [11]

The Design Basis Review makes a comparison between HFE related guidance used to inform the SMR-300 design, and the equivalent UK standards and guidance captured in the TAD [10].

17.7.2 Narrative

The HFIP [38] captures a review of HF related activities listed in the SMR-160 HFE PMP [22] against the ONR SAPs [23] in Appendix A. The most significant differences are related to the RGP linked to HRA in the safety assessment process, which are discussed further in the HRA review documentation, see sections 17.4 and 17.5.

The preliminary reviews of UK and US related guidance and legislation in the TAD [10] and Design Basis Review [11] confirmed minor differences in US/UK anthropometric data and design guidance, but these being manageable during detailed design with appropriate support from the HF teams. Any future design changes will be managed in accordance with the Design Management Process [40].

The evidence above supports the claim that the HF delivery framework defined in the SMR-160 HFE PMP [22] has been compared against the ONR SAPs and shown to be fundamentally comparable with the exception of the HRA process, against which a commitment has been raised in section 17.5 (C_Huma_003).

17.7.3 CAE Summary

HF design and assessment has taken cognisance of RGP and Operating Experience (OPEX). HF RGP is primarily based on information in NUREG-0711 and NUREG-0700, which are based on recognised US and International guidance. Applicability of that guidance to the UK has been judged based on a review carried out in the TAD and design basis. The review considered guidance including, but not limited to, information from British Standards and HSE guidance at a level considered suitable for PSR and provides sufficient confidence that design risk is manageable beyond GDA.

OERs captured in the HFE PMP [22] ensure that OPEX from the US fleet and international sources (e.g. sourced from INPO) are appropriately documented and considered in the design. The level of detail is considered to be appropriate for a PSR level review and for UK context.

17.8 DESIGN SUBSTANTIATION

Claim 2.2.8.3: Requirements relevant to Human Factors are identified and substantiated in a risk proportionate manner.

Claim 2.2.8.3 has not been further decomposed and is addressed directly as a single argument against the Level 4 claim.

17.8.1 Evidence for Argument 2.2.8.3

SMR-160 Human Factors Engineering Program Management Plan (HPP-160-1014) [22]

This document defines the delivery framework used by the HFE team for delivery of HF input to SMR-300, including processes for performing OERs, FRAs, FAs and TA in a systematic and auditable manner. These activities are used to analyse HAs and associated user needs, including the translation of functional and task requirements into HSI design requirements. These requirements are verified during a HF V&V programme, the purpose of which is to verify that the plant design conforms to HFE design principles and enables plant personnel to successfully perform their tasks to assure plant safety and operational goals.

Holtec SMR-300 GDA Target Audience Description (HI-2240729) [10]

The TAD provides a high-level description of the expected UK population as well as relevant Standards and Guidance directly applicable to the UK that are relevant to HF. This provides a baseline against which comparisons can be made between UK HF RGP and HFE related guidance currently used in the design of SMR-300, allowing judgements to be made on the suitability of associated design requirements for a UK context.

Holtec SMR-300 GDA Human Factors Design Basis Review (HI-2240732) [11]

The Design Basis Review makes a comparison between HFE related guidance used to inform HFE related requirements for the SMR-300 design, and the equivalent UK standards and guidance captured in the TAD. This provides a preliminary indication of design challenges introduced by the use of NRC accepted standards within a UK context. It concludes that differences identified are typically small and not expected to require significant changes to fundamental SMR-300 reference design at GDA.

Summary of Claims Placed on System Users for SMR-300 (HI-2240727) [34]

The Summary of Claims outlines a structured process for developing an Operational Task Schedule, a live document designed to support the tracking and management of identified HAs that will provide a basis for management of HFE related requirements. This schedule will underpin the Nuclear Safety, Security and Environmental Claims for the SMR-300 and inform the derivation of system requirements. The document establishes a clear traceability path, detailing how HAs are:

- Identified and characterised by risk significance.
- Screened and assessed.
- Represented in both the DSA and PSA.

Additionally, it includes supplementary information describing each HA's key attributes, such as type, location, purpose and, where applicable, HEPs. The schedule will also provide links to relevant HFE assessments, which may generate HF-related requirements.

17.8.2 Narrative

HF requirements are a tool used for the delivery of criteria important to the design of the SMR-300. Having a HFE process, such as that in the Holtec HFE PMP [22], ensures design criteria linked to established RGP for HF and task demands accounting for the physical and psychological needs of the system users is provided in an auditable manner. This includes the physical characteristics of the user population and cultural conventions linked to the operation of equipment. Given that the SMR-300 is based on criteria primarily derived from a US and international population, it is important to ensure the needs of a UK specific population are also reflected in the design, which is considered by the TAD [10] and Design Basis Review [11].

HF related SMR-300 requirements are derived based on criteria from a variety of sources. The process for initial development of requirements is included in procedures which dictate reference to HF design standards and outputs for use in development of System Design Descriptions (SDDs) (HPP-160-3001-R4) [45] and Control System Description (CSDs) (HPP-8002-3007) [46]. The PMP describes how the outputs of FRA, TA and HRA derive detailed requirements and how these are fed back into updated documentation (e.g. SDDs and CSDs) as the design develops. This is an iterative process.

The following documentation shows the hierarchy of requirements for the MCR and Ancillary Stations:

- SMR-300 Top Level Plant Design Requirements (HI-2240251) [25].
- SDD for the MCR and Ancillary Stations (HI-2240457) [47].
- System Specification for Monitoring and Operation (HI-2220303) [48].

The SDD for the MCR and Ancillary Stations defines the design requirements of the MCR and the Ancillary Stations. The System Specification for Monitoring and Operation describes the design basis of the safety and non-safety related HSI system.

Other sources of HF requirements, such as OERs, FRAs, PSA and DSA, are still under development. These are captured in SDDs or Specifications. HF requirements for an SMR-300 built in the UK will also be derived in the form of HF Safety Functional Requirements (SFRs) developed as part of a full Fault Schedule (see PSR Part B Chapter 14 [12]).

Substantiation that HF requirements have been met will be demonstrated by assessments undertaken such as TA, V&V and Integrated Systems Validation (ISV) in support of future design and licensing stages. This also applies to the identification and substantiation of HAs and administrative controls that impact safety and the maturity of the qualitative TA and quantification used to assess them. The Summary of Claims report provides the outline of a strategy for capturing the most significant claims, including their origin and how their achievability has been demonstrated.

The evidence above supports the claim that requirements relevant to HF are identified and substantiated in a risk proportionate manner.

17.8.3 CAE Summary

Requirements relevant to HF will be identified and substantiated in a risk proportionate manner by undertaking the following:

- Identification of HSI requirements in SDDs or Specifications.
- Identification of HF SFRs in the Fault Schedule.
- Identification of Human Based Safety Claims (HBSC) and associated SAs
- Substantiation of these requirements by providing evidence of the qualitative assessments undertaken.

This provides confidence that a systematic process is being applied, which will identify all significant HAs and that these will be substantiated in the design.

17.9 OPERATING PHILOSOPHY AND CONCEPT OF OPERATIONS

Claim 2.2.8.4: Staffing and Qualification requirements are systematically assessed and informed by Human Reliability Assessment.

Claim 2.2.8.4 has not been further decomposed and is addressed directly as a single argument against the Level 4 claim.

17.9.1 Evidence for Argument 2.2.8.4

SMR-160 Human Factors Engineering Program Management Plan (HPP-160-1014) [22]

Appendix D of the HFE PMP [22] provides a systematic approach for assessing and defining S&Q requirements which will be applied for the SMR-300 design. This will include the development of a Con Ops which will provide an overview of how the plant will be operated.

Operating Philosophy Review (HI-2240731) [39]

The Operating Philosophy Review for the Holtec SMR-300 outlines the fundamental approach to plant operation, staffing, and human-system interaction in support of GDA. It summarises available information on operational roles, responsibilities, staffing levels and key facilities, emphasising the use of passive safety systems and high automation to reduce operator burden. A key focus is the integration of HFE processes, including TA and HRA, to systematically inform S&Q requirements. The report demonstrates how the design and staffing philosophy align with UK licensing expectations.

17.9.2 Narrative

The HFE PMP [22] provides the criteria and guidance for technical content and structure for performing the S&Q analysis. It describes the methodology which will be used to ascertain appropriate licensed operator staffing levels to operate the plant safely and efficiently in all operating modes and conditions. The major steps in completing the S&Q Analysis include:

[REDACTED]

The Operating Philosophy Review [39] highlights the use of HRA within the broader HFE process to evaluate the likelihood of Human Failures and to assess the impact of staffing levels on human performance in a systematic manner. The use of HRA outcomes to help determine the minimum staffing required to safely perform tasks is also demonstrated, showing that staffing requirements are informed by the results of this systematic assessment.

Although the detailed Con Ops and final staffing analysis are still in development, the evidence available at GDA provides confidence that S&Q requirements are being developed in a manner broadly aligned to regulatory expectations in the UK, using HRA as a critical input to ensure safe and effective plant operation.

17.9.3 CAE Summary

The HFE PMP [22] describes the process for undertaking a systematic analysis of S&Q requirements, which take account of HRA output. The Operating Philosophy Review [39] demonstrates the application of fundamental HFE output in the definition of required operational tasking, roles, responsibilities, staffing levels and qualifications.

17.10 CHAPTER SUMMARY AND CONTRIBUTION TO ALARP

This sub-chapter provides an overall summary and conclusion of the HF chapter and how this chapter contributes to the overall demonstration of ALARP for the generic SMR-300. PSR Part A Chapter 5 [6] sets out the overall approach for demonstration of ALARP and how contributions from individual chapters are consolidated. This sub-chapter therefore consists of the following elements:

- Technical Summary.
- ALARP Summary.
  - Demonstration of Relevant RGP.
  - Evaluation of Risk and Demonstration Against Risk Targets.
  - Options Considered to Reduce Risk.
- GDA Commitments.
- Conclusion.

A review against these elements is presented below under the corresponding headings.

17.10.1 Technical Summary

PSR Part B Chapter 17 aims to demonstrate the following Level 3 claims to a maturity appropriate for a PSR.

Claim 2.1.7: Human actions important to safety and factors likely to influence human performance are systematically identified and their reliability and effective task performance is considered to be achievable.

Claim 2.2.8: Human factors requirements are integrated into the design, operation and maintenance of the generic Holtec SMR-300.

The Holtec process for identifying and assessing HAs important to nuclear safety and integrating Human Factors requirements have been reviewed against UK regulatory guidance for this PSR. The process has been summarised at a fundamental level, with examples of its application provided where possible, and in line with expectations for a PSR and GDA Step 2.

The Level 3 claims have been demonstrated by summarising the evidence available for each of the Level 4 claims, which collectively show that the Level 3 claims are met. The Level 4 claims are discussed below.

Claim 2.1.7.1: Human failures shall be systematically identified using Relevant Good Practice methodologies in a risk proportionate manner.

The Holtec design philosophy has been to minimise the reliance placed on the human to deliver nuclear safety. It is therefore anticipated that significant safety claims on HAs will be eliminated.

The approach used for identifying HAs is equivalent to that typically used in the UK HRA process as demonstrated in the HRA Methodology Review [32], but a commitment has been raised (C_Huma_003) to develop a HRA Strategy for the UK SMR-300 design, which should include further consideration of this process.

Claim 2.1.7.2: Human Reliability Assessment shall be undertaken to determine the reliability and effective task performance of human actions in a risk proportionate manner.

The majority of human failure events modelled in the SMR-160 PSA based on identified HAs have received treatment using either the ASEP or SPAR-H, which are considered to be adequate methods.

PSA demonstrates that the overall contribution to risk from HAs is not significant, and the design does not place reliance on HAs as the primary means to achieve nuclear safety.

The substantiation of human failures has not been possible due to the low level of safety related claims and the maturity of the UK based safety assessment for PSR. The Holtec approach undertaken for SMR-160 provides confidence that substantiation could be made in the future once further HRA data is available. Commitment C_Huma_003 has been raised to develop a HRA Strategy for the UK SMR-300 design, describing how to make use of the processes for deterministic and PSA used by the NRC, as well as information relating to the TIHAs in UK safety assessment.

Claim 2.2.8.1: Human Factors Relevant Good Practice is appropriately integrated into the generic Holtec SMR-300 lifecycle.

A key part of the HF work undertaken in support of the PSR has been reviewing the HFE process as defined in the SMR-160 HFE PMP [22] against UK regulatory expectation and demonstrating evidence of its application. The reviews presented in the Step 2 deliverables demonstrate that the approaches to HFE and HRA broadly comply with ONR guidance. A HFIP was produced to define the tasks to be undertaken by Holtec during GDA Step 2.

HF considerations raised during development of Step 2 outputs have been reviewed and the Holtec risk management process [43] applied to identify associated risks, which have been captured in the Risk Register. Considerations that involve changes to fundamental aspects of the SMR-300 design, design process, or operational characteristics, specifically those necessary to meet UK context requirements within the scope of GDA, have been identified as commitments.

The HRA Position Statement [30] presents a conclusion on the adequacy of evidence collected within the scope of the HRA programme against RGP. FA and TA for four key systems have been assessed and are broadly in-line with ONR guidance.

Claim 2.2.8.2: Human Factors design and assessment shall take cognisance of Relevant Good Practice and Operational Experience.

The high-level activities defined in the HFE PMP [22] broadly align with guidance in key ONR SAPs (e.g. EHF1 to 12). Minor deviations from expectation for HRA process were found and raised as HF considerations, which have been managed through the project risk management process [43] and have resulted in a GDA commitment relating to HRA strategy and implementation: C_Huma_003.

Holtec have used US and international guidance to inform HFE criteria as well as output from OERs. There are some differences between US and UK HF RGP, such as cultural conventions and minor differences between population sizes, which are outlined in the Design Basis

Review [11]. The differences noted are considered to be minor and manageable through the project design challenge process during future licensing stages.

Claim 2.2.8.3: Requirements relevant to Human Factors are identified and substantiated in a risk proportionate manner.

Requirements relevant to HF will be identified and substantiated in a risk proportionate manner by undertaking the following:

- Identification of HSI requirements in SDDs or Specifications.
- Identification of HF SFRs in future Fault Schedule development.
- Identification of HBSCs and associated SAs.
- Substantiation of these requirements by providing evidence of the qualitative assessments undertaken.

Substantiation of these requirements will be undertaken by providing evidence of the qualitative assessments undertaken as the design matures. All safety related HAs will be logged in the Operational Task Schedule described in the Summary of Claims document [34].

Claim 2.2.8.4: Staffing and Qualification requirements are systematically assessed and informed by Human Reliability Assessment.

The Operating Philosophy Review [39] describes the integration of HFE processes, including TA and HRA, to systematically inform S&Q requirements. It describes the approach to plant operation, staffing, and human-system interaction and demonstrates how the design and staffing philosophy align with UK licensing expectations.

17.10.2 ALARP Summary

17.10.2.1 Demonstration of the use of RGP

The HFE activities for the generic SMR-300 have been undertaken in accordance with the NUREG-0711 HFE Program Review Model [37]. NUREG-0711 is considered best practice by the NRC and provides a robust starting point for the evaluation of the SMR-300 as deployed in the UK.

The HFE activities listed in the HFE PMP [22] broadly cover the areas listed in ONR SAPs. The most significant differences between NRC and ONR regulatory guidance relate to the safety assessment process, which prompted the review of the HRA processes. A comparison between the SMR-300 HFE process and the ONR SAPs [23] was undertaken to demonstrate that the approach is consistent with expectations for HRA in the UK. This highlighted areas where there are no activities equivalent to UK RGP. These are discussed in the following section.

17.10.2.1.1 Identification and Classification of HBSCs

HAs important to safety and administrative controls are commonly referred within the UK nuclear industry as HBSCs. The NRC approach for HRA does not have an equivalent of HBSCs which are defined in Section 3.3 of NS-TAST-GD-006, Design Basis Analysis [49]. However, HAs can be viewed as equivalent to SAs, as defined in Section 5.1 of NS-TAST-GD-063, Human Reliability Analysis [50]. SAs are conceived and implemented to articulate

the specific steps of a task required to achieve an HBSC and provide clear boundaries for undertaking HRA. HAs identified for the generic SMR-300 can therefore be used as the basis for SAs in a UK context.

17.10.2.1.2 Substantiation of Claims

The NRC approach does not include a direct equivalent for human claims substantiation therefore V&V is used to underpin human performance and the reliability of HAs. An equivalent approach to substantiation of claims has been proposed based on information available, which is presented in section 4.3 of the HRA Methodology Review [32] and will be considered as part of the commitment to develop an HRA strategy, as outlined in C_Huma_003.

17.10.2.2 Evaluation of Risk and Demonstration Against Risk Targets

The numerical targets against which the demonstration of ALARP is considered can be found in PSR Part A Chapter 2 [3].

SSCs associated with HBSCs will contribute to the demonstration of ALARP by comparison against the risk targets in two ways:

- By fulfilling safety functions for normal operations (e.g. reduction of normal operation dose uptake by minimising the time operators spend in high dose rate areas) and thereby contributing to achieving Targets 1-3.
- By achieving the target value linked to the associated HBSC they will contribute to the achievement of accident risk, Targets 4-9.

The evaluation of the normal operations and accident risks against Targets 1-9 is summarised in PSR Part A Chapter 5 [6].

Risks below the Basic Safety Objectives (BSOs) are considered broadly acceptable; however, consideration will be given to reducing risks in a proportionate manner where appropriate. Risks between the BSOs and Basic Safety Levels (BSLs) require a consideration of risk reduction options. Risks above the BSLs are not acceptable.

Numerical targets have not been assessed in detail for PSR v1. Evaluation of quantitative risk is captured in PSR Part B Chapter 16 [14]. HRA and error quantification will be required for the PSA to calculate HEPs that will form part of the overall comparison against the risk targets.

At this time, the evaluation of the normal operations and accident risks against Targets 1-9 has not been assessed in detail. This information will be presented in future iterations of PSR Part B Chapter 10 Radiological Protection [51] for normal operations, and PSR Part B Chapters 14 [12], 15 [13] and 16 [14] for accident conditions.

17.10.2.3 Options Considered to Reduce Risk

The process for assessment of risk reduction options is presented in Holtec's Design Management Process [40]. Part A Chapter 5 [6] considers the holistic risk-reduction ALARP process for the generic SMR-300.

A review of design challenges raised as part of the Design Management Process [40] has been undertaken to assess whether any of the challenges have an impact on the HF topic. At this stage of the SMR-300 design, no HF specific challenges have been identified that may

lead to a reduction in risk. Risk reduction options will be identified once HAs have been modelled in the DSA and PSA analyses and ALARP studies can be undertaken to optimise the risk.

17.10.2.4 GDA Commitments

HF considerations have been reviewed and the Holtec risk management process [43] applied to identify all potential risks associated with these considerations, which have been captured in the Risk Register. Considerations that involve changes to fundamental aspects of the SMR-300 design, design process, or operational characteristics, specifically those necessary to meet UK context requirements within the scope of GDA, have been identified as commitments. Commitments, Assumptions and Requirements are captured in the CAR Register [42].

It has been noted that US HRA outputs for the SMR-300 will not be available for review within GDA timeframes and as such cannot be integrated with UK safety assessment processes, which HRA must effectively support and integrate with. A Commitment has therefore been raised to develop a HRA Strategy for the UK SMR-300 design, as outlined below.

C_Huma_003: The SMR-300 design, and underlying design processes demonstrate that human risks are systematically identified, proportionately assessed, and that the risk contribution from operator actions is tolerable. It is noted that US Human Reliability Assessment (HRA) outputs for the SMR-300 will not be available for review within GDA timeframes and as such cannot be integrated with UK safety assessment processes which HRA must effectively support and integrate with. A commitment is raised to develop a HRA Strategy for the UK SMR-300 design, describing how to make use of the processes for deterministic and probabilistic safety assessment used by the NRC, as well as information relating to the Treatment of Important Human Actions in UK safety assessment. Target for Resolution - Issue of UK Pre-Construction Safety Report.

The need for integration of HFE within the safety assessment to appropriately address UK expectations and good practice is recognised within PSR Part B Chapter 14 under commitment C_Faul_103 on Fault Studies. As the current HRA process is not completely aligned with UK RGP (discussed further in the HRA position statement [30]) and the UK safety assessment process is not yet finalised, it is not yet possible to demonstrate that HRA output can be fully integrated.

17.10.3 Conclusion

This chapter summarises the approach for application of HF to the fundamental SMR-300 design in the UK. It identifies the claims and arguments that will form the basis of the safety case for the HF topic throughout the lifecycle of SMR-300 to a maturity aligned to a PSR.

As demonstrated throughout, the claims and arguments presented have been supported with evidence sufficiently mature for a PSR. This is contingent on delivery of one HF commitment, which has been raised to develop an HRA strategy which makes use of US outputs when available and to integrate with safety assessment for the SMR-300 design in a manner consistent with UK-recognised RGP and regulatory expectations.

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17.12 LIST OF APPENDICES

Appendix A PSR Part B Chapter 17 CAE Route Map

Table 2: PSR Part B Chapter 17 CAE Route Map

[REDACTED]